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1100 NEW YORK AVENUE, N.W.  
WASHINGTON, DC 20005

EXAMINER
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MARVICH, MARIA

ART UNIT	PAPER NUMBER
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1633

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09/04/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/806,346	<b>Applicant(s)</b> URTHALER ET AL.	
	<b>Examiner</b> MARIA B. MARVICH	<b>Art Unit</b> 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 6/2/09.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 3-9, 11-20, 23, 24 and 40-48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3-9, 11-20, 23, 24 and 40-48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/16/09</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/16/09 has been entered.

Claims 3-9, 11-20, 23, 24 and 40-48 are under examination in this application.

### ***Claim Objections***

**The following objections are either new objections necessitated by applicants' amendment or are new objections.**

Claim 40 is objected to because of the following informalities: Claim 40 recites in the preamble purification from "a host cell". However, reference throughout the claims is to "host cells". For clarity, it would be remedial to refer to the cells either in singular or plural to ensure proper antecedent basis.

Mention is made to introducing or transporting of solution into the reactors. However, there is no recitation of how the solutions are introduced or transported. According to the specification pumps or pressurized gas transport the solutions from one reactor to the next. Hence, it would be remedial to introduce into the preamble the phrase, --wherein transportation between the reactors is mediated by pressure or pumps--.

Claim 8 is drawn to methods of increasing pressure by applying pressurized air. However, it is dependent on claim 48 which already recites that pressure is increased by applying

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pressurized air. Hence, it appears as if the method of claim 8 is in addition to the method of claim 48 and therefore, it would be proper to recite ----is also increased by applying pressurized air--.

In claim 18, the recitation of “a concentration step” and “a condition step” refer to limitations previously recited in claim 17. When referencing limitations previously recited, it is proper to use the article "the" as newly recited limitations are referenced using the article "a" or "an". Therefore, it would be remedial to use the article --the--.

Claim 23 recites that step a) is “operated” in a continuous mode. However, step a) comprises several parts and it is not clear which part is operated continuously. It would be remedial to indicate what step is continuous.

Claim 24 recites that the cell suspension obtained in step a) is cryo-pelleted. However, it is not clear when the suspension is cryo-pelleted. It appears as if prior to use in step a) the suspension was previously cryo-pelleted. If so, it would be clearer to indicate that the cell suspension is obtained from a cryo-pelleted cell suspension.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 40 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 40 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: how the cell suspension and lysis solution are “homogenously mixed as a result of flowing through the filling elements in the lysis reactor so that irreversible denaturation of the biomolecule is avoided and the cultivated host cells are disintegrated by alkaline lysis in the absence of shear forces”. The claim requires these three events in the lysis reactor 1) homogenous mixing of the suspension with lysis solution 2) avoidance of irreversible denaturation of the biomolecule and 3) disintegration of the host cells by alkaline lysis without shear force. The claims appear to suggest that these effects are the result of flowing through the filling elements. If this is the case, this presents issues of new matter discussed below. If this is not the case, there appear to be critical elements and steps that are lacking in the claims.

1) Homogenous mixing of the suspension with lysis solution is taught by the specification to be critical. However, this step is not an inherent property of flow through the lysis filling elements as the claim sets forth.

¶0029 To enhance homogenous mixing of the cells with the lysis solution, especially designed static mixers are suggested. These devices are commercially available continuous flow-through supports.

In fact, homogenous mixing is not clearly easily attained.

¶0046 The devices used in these methods for contacting the solutions during lysis and neutralization do either not guarantee homogenous mixing or may apply disadvantageous shear forces to the solutes.

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Hence, the instant specification appears to be directed to steps to ensure homogenous mixing.

For this purpose, a novel neutralization reactor, which is also subject of the invention, is used. This reactor consists of a connector means and a tubing system, which is designed such that homogenous mixing of lysed cell solution.

However, it is not quite clear what exact steps are made to avoid the problems with an inability to generate homogenous mixing with methods found in the art.

2) As well, the claim requires avoiding irreversible denaturation of the biomolecule during lysis. The specification teaches that denaturation results accordingly,

¶0022 The alkaline conditions lead to denaturation of pDNA by unwinding the supercoiled structure. Up to a pH-value of 12 to 12.5 the complete separation of the complementary strands is prevented. This enables entire renaturation of the plasmid molecule, when the pH is decreased again. If the pH-value exceeds the renaturation limit, the unseparated regions are lost and the pDNA is irreversibly denatured.

However, there also appears to be some mechanical or technical means of controlling degradation.

¶0094 The parameters of step b) and the dimensions of the device used therein are advantageously designed such that homogenous mixing is guaranteed and contact time is kept in a certain range from 5 seconds to 5 minutes or more, preferably at 1 to 3 minutes, in order to avoid denaturation of the desired polynucleotide. These parameters can be adjusted by the dimension of the device, the free volume between the packed beads and the flow rate. The contact time for adequate alkaline lysis of cells depends on the host strain and is independent of the biomolecule of interest, in the case of pDNA it is independent of plasmid size or the plasmid copy number (PCN).

However, it is unclear what in the method is required to ensure the avoidance.

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3) Disintegration of the host cells by alkaline lysis without shear force is taught by the specification in ¶ 0019 to require specific steps and is avoided by avoiding specific methods as taught in ¶ 0031. Otherwise steps at the neutralization, clarification or optional conditioning steps discuss methods to avoid disadvantageous shear force.

“High-pressure homogenization, the most common technology for the recovery of proteins, cannot be used for polynucleotides due to their size-depending shear force sensitivity and possible destruction of gDNA.” “Thermal treatment of the cells is another option for a disintegration technique that avoids shear forces, as described in WO 02/057446 A2 and WO 96/36706.”

The methods using static mixers (or reduced tubing diameters) may cause high shear forces to the polynucleotides.

A further unexpected result was obtained when procedures for mixing the lysed cell solution with the neutralization solution were tested. It was found that after connecting the streams of the pumped lysed cell solution with the stream of the pumped neutralization solution by a conventional T- connector, an especially specially oriented tubing results in satisfactory mixing of the solutions and formation of compact voluminous flocks, which are not influenced by strong shear forces.

Hence, the claims recite desired outcomes without indicating how these steps are achieved.

Secondly, the claims do not indicate how the suspension is introduced and transported into the lysis reactor, neutralizing reactor or clarification reactor. In order for the suspension to move between reactors there has to be some kind of force or power.

### ***Claim Rejections - 35 USC § 112, first paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 40 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The limitation that “homogenously mixed as a result of flowing through the filling elements in the lysis reactor so that irreversible denaturation of the biomolecule is avoided and the cultivated host cells are disintegrated by alkaline lysis in the absence of shear forces” has been added to claim 40. An interpretation of this phrase is that passage through the filling elements leads to 1) homogenous mixing of the suspension with lysis solution 2) avoidance of irreversible denaturation of the biomolecule and 3) disintegration of the host cells by alkaline lysis without shear force. Applicant has not indicated where support for this limitation is found. The examiner has been unable to find support in the originally filed specification for this effect. Therefore, the limitation is impermissible NEW MATTER.

“It is not sufficient for purposes of the written description requirement of Section 112 that the disclosure, when combined with the knowledge in the art, would lead one to speculate as to modifications that the inventor might have envisioned, but failed to disclose.” *Lockwood v. American Airlines Inc.*, 41 USPQ2d 1961, 1966 (CAFC 1997). Therefore, the limitation is impermissible NEW MATTER.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:



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A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 3-5, 7-9, 17-2023, 40, 42, 43, 47 and 48 are rejected under 35 U.S.C. 102(b) as being anticipated by Petersen et al (US 6,893,879; see entire document). **This is a new rejection.**

Petersen et al teach a method of purification of a biomolecules from samples such as E. coli (see e.g.). The sample is thus inherently isolated from fermentation broth as the cells are grown in such media (see instant specification ¶ 0016 in the PGPUB). The method is performed on a continuous flow automated cartridge that comprises chambers for lysis, neutralization and “extraction” or “capture” (see e.g. col 9, line 15-36; col 10, line 25-30 and col 12, line 58-65). Samples are introduced into a lysis chamber or channel which can include filling elements such as glass beads (see e.g. col 3, line 35 and col 16, line 12-25) as is lysis buffer (see claim 5). The clarification chamber uses a retention layer such as a filter or flocculation that can comprise particulate matter such as beads (see e.g. col 16, line 48-64). The cartridge includes flow controllers (see e.g. col 3, line 4-5) and utilizes pressure such as air or gas (see e.g. col 8, line 19-34) and wash solutions (see e.g. col 17, line 25).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3-5, 7-9, 11-20, 23, 40, 41-43 and 46-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petersen et al (U.S. Patent No. 6,893,879; see entire document) in view of Nochumson et al (US 20060106208; see entire document).

The instant methods are directed towards methods of manufacturing a biomolecule using a system wherein lysis buffer and sample are introduced into a reactor for lysis. The teachings of Petersen et al are as above except Petersen does not establish how the sample and lysis buffer are introduced.

Nochumson et al teach methods of purification of biomolecules using automated and semi-automated continuous units, which given the broadest interpretation can be considered reactors as the described reactions are undertaken in these units. As demonstrated in figure 2 and described in ¶ 0041, the cell suspension is loaded and undergoes alkaline lysis following which neutralization occurs. Following this, the lysate is clarified from precipitated cellular debris and impurities (RNA, chromosomal DNA, endotoxin, denatured plasmid). In these steps, the DNA flows through while the impurities remain in the column. The method is performed on a continuous, flow-through device (see e.g. 0019) in which resuspended cells, lysis solution and neutralization solutions are mixed using continuous flow, in line. Nochumson et al teach that

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lysis solution and cells can either be combined without further mixing prior to entering the lysis reactor (see e.g. 0055) or else can be introduced into the lysis reactor and combined for example by use of an impeller mixer (see e.g. ¶ 0036). In the case that the two are part of two independent flows that are mixed in the lysis reactor, one of skill in the art would recognize that these flows would reasonable make a single flow to an inline static mixer by use of a T or Y shaped connector these being configurations that would lead to a single flow (see e.g. ¶ 0055 and figure 1). Effluent from the lysis reaction was directed to neutralization which Nochumson et al teaches occurs by flowing lysate and neutralization solution through an inline state mixer in a continuous mode wherein a continuous flow indicates that flow is constant (see e.g. ¶ 0080).

The lysate is clarified and this is said to occur by a variety of techniques known to those of skill in the art (see e.g. ¶ 0072-0073 and 0063). This occurs through fluid connections between the units (see e.g. ¶ 0019-0021 and 0054). As well pumps are used to distribute the lysate and mixtures throughout the method. Claim 24 recites that the cells at step a) are cryo- pelleted. It is understood that this intends that the cells prior to use are cryo-pelleted. Nochumson et al teach that the cells can be frozen prior to use in the lysis reaction (see e.g. ¶ 0078) and in the broadest interpretation, these can be cryo-pelleted cells. Nochumson teaches that clarification occurs for example following alkaline lysis and neutralization by separation of the precipitated impurities by subsequent chromatographic steps (see e.g. ¶ 0048). The chromatographic step uses reactors comprising particulate material. Several wash steps are included as is clarification and concentration (see e.g. ¶ 0050-0053).

As an initial point, KSR forecloses the argument that a specific teaching, suggestion or motivation is required to support a finding of obviousness. See the recent Board decision *Exparte*

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Smith --USPD2d--, slip op. at 20, (BD. Pat. App. & Interfer. June 25, 2007). In this case, both Petersen and Nochumson et al teach methods of isolating biomolecules using automated systems. While Petersen does not include the methods that are set forth in Nochumson, it is clear that the methods of introducing lysis buffer and sample into a reactor well known and available in the art as seen in Nochumson et al. One would have been motivated to do so in order as the ability to modify isolation methods by applying conventional methodologies was well known in the art. Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Claims 3-5, 7-9, 11, 17-20, 23, 40, 42, 43, 47 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petersen et al (U.S. Patent No. 6,893,879; see entire document) in view of Craig (U.S. Patent No. 6,381,967; see entire document). **This is a new rejection.**

Applicants claim a method to purify a biomolecule of interest wherein a cell mass obtained by cultivating host cells to produce the biomolecule are cryo-pelleted.

The teachings of Petersen et al are as above, Petersen et al do not teach cryo-pelleted samples to be used.

Craig teaches problems that cause cell death during cell freezing, including death due to formation of large sharp ice crystals, and also cell poisoning due to osmotic dehydration by formation of ice crystals. Craig teaches that freezing can involve a process of vitrification, which is the solidification of solutions at low temperature without ice crystal formation. Craig teaches that the higher the speed of the temperature change, the lower the viscosity required to vitrify

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and faster freezing rates lead to smaller ice crystals (see column 1, lines 16-44, for example).

Craig teaches that the goal of any cryopreservation process is to minimize cell damage (see column 2, lines 1- 30, for example). Craig teaches a freezing method in which a liquid sample is transformed into small drops that are directly contacted with a partially solidified refrigerant.

Craig teaches that this method is useful for substances that are susceptible to ice crystal or osmotic damage such as cells, plant material, tissue culture cells, sperm and embryos (see column 3, lines 20-25, column 4, lines 29-40, and column 12, lines 9- 20, see, for example).

It would have been obvious to the skilled artisan at the time the invention was made to use the rapid freezing method as taught by Craig to form bacterial cell cryo- pellets for storage prior to a method of biomolecule purification as Craig teaches an advantageous method of freezing cells. The motivation to freeze the bacterial cells by dropping them into partially solidified gas to form a cryopellet is the expected benefit of freezing the cells quickly in order to avoid formation of damaging and cytotoxic ice crystals as taught by Craig. There is a reasonable expectation of success to cryopellet bacterial cells before use since this has worked previously as taught by Craig. Given the teachings of the prior art and the level of skill of the ordinary skilled artisan at the time the invention was made, it must be considered that said ordinary skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

Claims 3-9, 17-20, 23, 40, 42, 43, 47 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petersen et al (U.S. Patent No. 6,893,879; see entire document) in view of Marquet et al (U.S. 5,561,064; see entire document). **This is a new rejection.**

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Applicants claim a method to purify a biomolecule of interest wherein a cell mass obtained by cultivating host cells to produce the biomolecule are clarified using glass beads or sinter plates.

The teachings of Petersen et al are as above. While, Petersen et al teach that lysates produced by alkaline lysis and neutralization are also clarified, Petersen et al do not teach that the filtrations utilize sinter plates.

The art is replete with methods for clarification of plasmid DNA as well as other biomolecules in which lysates are clarified from impurities are filtered through sinter plates. Marquet et al teach advances in filtration devices for purification of biomolecules. The filtration devices are scalable, remove contaminants, and do not rely upon addition of extraneous proteins such as RNase, organic extractants or mutagenic reagents (see e.g. bridging ¶ col 2-3). Marquet et al teach that cell debris and impurities can be removed from the lysate containing DNA by filtration through a material that is porous enough for plasmid DNA to pass through, but not insoluble material. Marquet et al teach that the filter device can be comprised of a porous fritted glass disks (see e.g. col 8, line 23-50). This method requires application of pressure for example which requires that pressure be placed above the filter to force outflow of the lysate and functions as a distribution means to force the lysate to reach the retention layer.

As an initial point, KSR forecloses the argument that a specific teaching, suggestion or motivation is required to support a finding of obviousness. See the recent Board decision *Exparte Smith --USPD2d--*, slip op. at 20, (BD. Pat. App. & Interfer. June 25, 2007). In this case, it would have been obvious to the skilled artisan at the time the invention was made to use the filter systems as taught by Marquet et al in the methods of Petersen et al because Marquet et al teach

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that using glass discs as well as glass beads was well known in the art and could be used in scale up methods and because Petersen et al teaches that a variety of methods for DNA clarification could be used in methods of purification of DNA. As well, it is within the ordinary skill of the art to use available methodologies to purify DNA and one would have been motivated to do so in order as the ability to modify the purification systems by applying conventional methodologies was well known in the art. Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Claims 3-5, 7-9, 17-20, 23, 40, and 42-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petersen et al (U.S. Patent No. 6,893,879; see entire document) in view of Laugharn et al (US 6,274,726; see entire document). **This is a new rejection.**

Applicants claim a method to purify a biomolecule of interest wherein a cell mass obtained by cultivating host cells to produce the biomolecule are clarified using glass beads.

The teachings of Petersen et al are as above. While, Petersen et al teach that lysates produced by alkaline lysis and neutralization are also clarified, Petersen et al do not teach that the beads are uniform and are about 1-100  $\mu$ m.

Laugharn et al teach use of glass beads for lysis of samples for purification methods. Laugharn et al teach that the beads are about 1-100  $\mu$ m in size and hence must be uniform in size (see e.g. col 28, line 34-62). As an initial point, KSR forecloses the argument that a specific teaching, suggestion or motivation is required to support a finding of obviousness. See the recent Board decision *Exparte Smith --USPD2d--*, slip op. at 20, (BD. Pat. App. & Interfer. June 25,

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2007). In this case, it would have been obvious to the skilled artisan at the time the invention was made to use the lysis methods of Laugharn et al in the methods of Petersen et al because Laugharn et al teach that using beads of about 1-100 mm was well known in the art and could be used in purification methods and because Petersen et al teaches that a variety of methods for DNA clarification could be used in methods of purification of biomolecules. As well, it is within the ordinary skill of the art to use available methodologies to purify DNA and one would have been motivated to do so in order as the ability to modify purification systems by applying conventional methodologies was well known in the art. Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARIA B. MARVICH whose telephone number is (571)272-0774. The examiner can normally be reached on M-F (7:00-4:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, PhD can be reached on (571)-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Maria B Marvich, PhD  
Primary Examiner  
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Primary Examiner, Art Unit 1633